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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/494,374 01/31/00 COMPADRE

C 23533/119

EXAMINER

HM22/0718

FOLEY & LARDNER
3000 K STREET N W SUITE 500
Washington DC 20007-5109

MCQUEENEY, P

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/494,374

Applicant(s)

COMPADRE ET AL.

Examiner

P. E. McQueeney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Acknowledgement is made of applicants' amendment and request for reconsideration filed April 30, 2001 and supplemental information disclosure statement filed December 29, 2000.

Claim Objections

2. Applicant is advised that should claims 31-33 be found allowable, claims 44-45 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

3. Claims 1-8, 10-13, 25-27, 31 and 34-38 were rejected under 35 U.S.C. 102(b) as being anticipated by Hall (US 5,405,604). Hall discloses a concentrated mouthrinse. Hall discloses applicant's claims 1-8, 10-13, 31 and 34-38 in claim 1 (about 0.05% to about 10.0% cationic antimicrobial agent; about 30 to about 85% of propylene glycol, polyethylene glycol, and mixtures thereof; water). Hall discloses applicant's claim 25-27 in claim 2 (cetylpyridinium chloride and tetradecylpyridinium chloride and mixtures thereof).

Applicants have amended claim 1 by deleting "about" from "a quaternary

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compound with a concentration from greater than about 10% by weight.” However, Hall claims a concentration from about 0.05% to about 10.0%. Therefore, although applicants’ lower limit is greater than 10%, Hall still reads on applicants’ claim because of the term “about” in his claim.

Applicants’ arguments regarding the flavoring oil are persuasive.

This rejection is maintained as to claims 1-8, 10-13 and 25-27.

4. Claims 1-13, 21, 25-27, 31, 34-39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan (US 4,472,373). Ryan discloses oral compositions, such as toothpastes, mouthwashes, lozenges and chewing gum containing an antimicrobial agent which is effective against plaque/gingivitis and mouth odor (abstract). Ryan discloses an oral composition comprising a safe and effective amount of an antimicrobial and a pharmaceutically acceptable carrier (col. 1, lines 60-68). Ryan discloses that the antimicrobial of his invention includes N-tetradecylpyridinium salt and/or a N-tetradecyl-4-ethyl-pyridinium salt (col. 2, lines 4-7). Ryan discloses that the concentration of antimicrobial in his formulation can range from 0.001% to about 20% (col. 2, lines 57-60). Ryan discloses that mouthwash formulations generally comprise about 20:1 to about 2:1 of a water/ethyl alcohol solution (col. 4, lines 14-16). These disclosures read on applicants’ claims 1-13, 21, 25-27, 31, 34-39 and 44.

Claim Rejections - 35 USC § 103

5. Claims 1-39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hall, as discussed above, in view of Dickson (US 5,520,575).

Hall discloses a maximum concentration of cationic antimicrobial agent of about 10%. Hall does not disclose a concentration of cationic antimicrobial agent of about 15% (applicant's claim 9); about 20% (applicant's claim 21); and about 40% (applicant's claims 14-16, 20, 24 and 32). Dickson teaches at col. 4, lines 12-35 that the concentration of antimicrobial agents typically range from about 1 to about 30%. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the concentration of the antimicrobial agent and delivery mechanism based on its intended purpose. The expected result would be a successful product.

Hall does not disclose spraying or misting his product. It is the position of the examiner that all liquid products are sprayable or mistable. As Hall's product is a liquid, this meets the limitations of applicant's claim 39.

Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

6. Claims 1-13, 21, 25-27, 31 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall, as discussed above, in view of Bevilacqua (US 5,693,315).

Hall discloses a maximum concentration of cationic antimicrobial agent of about

10%. Hall does not disclose a concentration of cationic antimicrobial agent of about 15% (applicant's claim 9) and about 20% (applicant's claim 21). Bevilacqua teaches mammal tooth treating compositions (title). Bevilacqua teaches at col. 2, lines 1-8 that the typical concentration of antimicrobial compound ranges from 0.75 to 20%. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the concentration of the antimicrobial compound based on the teachings of Bevilacqua that the concentration can range from 0.75 to 20%. The expected result would be a successful product.

Hall does not disclose spraying or misting his product. It is the position of the examiner that all liquid products are sprayable or mistable. As Hall's product is a liquid, this meets the limitations of applicant's claim 39.

7. Claims 1-39 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan and Hall.

Ryan discloses that additional ingredients may be included in his mouthwash at col. 4, lines 11-30, including humectants and flavoring agents. As humectants, Ryan lists glycerin and sorbitol (col. 4, lines 19-21) and other edible polyhydric alcohols (col. 3, line 66 through col. 4, line 2). Ryan does not explicitly list propylene glycol as said humectant. Hall requires polyethylene glycol and propylene glycol in his solvent system (col. 4, lines 56-59). Hall teaches at col. 4, lines 50-56 that his solvent system acts as a carrier for the flavoring oils because his solvent system solubilizes the flavoring oils and aids in dispersion of the flavoring oils. It would have been obvious to a person of

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ordinary skill in the art at the time the invention was made to include propylene glycol of Hall in the teachings of Ryan because Ryan teaches that polyhydric alcohols and flavoring agents can be included in his mouthwash and Hall teaches that propylene glycol helps solubilize the flavoring oil and disperse the flavoring oil. The expected result would be a mouthwash containing a uniform dispersion of flavoring oil.

Ryan discloses a maximum concentration of antimicrobial agent of about 20%. Ryan does not disclose a concentration of cationic antimicrobial agent of about 40% (applicant's claims 14-16, 20, 24, 32 and 45). In the absence of a showing of criticality, the step of varying the antimicrobial concentration in these claims is deemed to be an obvious parameter manipulatable by an artisan to obtain the best possible results.

Election/Restrictions

8. Claims 40-43 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. E. McQueeney whose telephone number is 703-306-5827. The examiner can normally be reached on M, T, H, F 7:45 AM to 6:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-3592 for regular communications and 703-308-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

pem
July 15, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600